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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,978	04/25/2001	Susana Salceda	DEX-0172	3638
32800	7590	12/28/2005	EXAMINER	
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			AEDER, SEAN E	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 12/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Detailed Action

The request filed on 11/22/05 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09/763,978 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 14-37 were pending.

Claims 15-20, and 29-34 have been cancelled by Applicant.

Claims 14 and 28 have been amended by Applicant.

New claims 38-49 have been added by Applicant.

Claims 14, 21-28, 35-49 are currently under consideration.

Claim Objections

Applicant, in addressing the objection to claim 14 for an inconsistency, has amended the claim to make it consistent with claim 28. Thus, the objection is withdrawn.

Response to Arguments

Claims 14, 21-28, 35-37 remain rejected and new claims 38-49 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial utility or a well established utility for the reasons of the previous Office Actions and for the reasons set-forth below.

The claims are drawn to isolated antibodies or antibody fragments that bind specifically to a protein encoded by polynucleotide SEQ ID NO:1 or to fragments of a protein encoded by SEQ ID NO:1 and a method for binding said antibodies to said protein or to fragments of said protein.

The Response filed on 11/22/05 has been carefully considered but is deemed not to be persuasive. The Response cites MPEP 2107.02 and states that utility of the claimed invention is set forth in detail in the specification (page 10 of Response). Applicant further cites Raytheon v. Roper and MPEP 2107.02 (page 10 of Response). Applicant further states the Office must establish that it is more likely than not that one of ordinary skill in the art would doubt (i.e. "question") the truth of the statement of utility in order to overcome the "presumption of truth that an assertion of utility by the applicant enjoys" (page 10 of Response). Applicants further state that "no such evidence that the statement of asserted utility for the instant claimed invention would be considered false by the skilled has been provided by the Examiner in the instant case" (page 10 of Response). In contrast, Applicants argue that confirming evidence by Tringler and Salceda (submitted in the response filed 5/3/05) demonstrate that the claimed invention is useful in the manner taught in the originally filed application (pages 10-11 of Response).

A Declaration from Dr. Susana Salceda accompanied the Response filed on 11/22/05. The Response indicates that the Declaration "makes clear that any

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experimentation necessary to make and use the invention as claimed was routine to the skilled artisan when coupled with the information taught in the specification” (pages 11-12 of Response). The Response, citing the MPEP and case law, further states that information well known in the art does not need to be described in detail in the specification (page 14 of Response). The Declaration suggests that one of skill in the art would “know that the open reading frame in the forward direction of SEQ ID NO:1 would be in a frame encoding for a Methionine near the 5’ end, encode many amino acids and terminate with a stop codon. Thus, any open reading frame of SEQ ID NO:1 with lots of stop codons can be ruled out since we know to look for a long open reading frame sequence beginning with an M and ending with a stop codon in accordance with the information taught in the patent application about SEQ ID NO:1” (page 3 of Declaration). The Declaration further suggests one of skill in the art had many tools available before the time of filing that would help identify potential open reading frames from a given sequence (page 3 of Declaration). Further, Dr. Salceda provided examples of computer-generated open reading frames using instant SEQ ID NO:1 (pages 4-5 of Declaration and attached examples). The Response states that these examples indicate that there was only one possible open reading frame for a full-length protein (page 13 of Response and frame 2 of Figure 2 from Declaration). The Response and Dr. Salceda further argue that SEQ ID NO:1 was not a “starting point(s) for further research and investigation into potential practical uses”, rather “the nucleotide sequence of SEQ ID NO:1 and the characteristics disclosed in the patent application about SEQ ID NO:1 were adequate to routinely and unambiguously obtain the protein

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sequence and then generate antibodies or antibody fragments thereto" (pages 5-6 of Declaration and page 14 of Response). It is further argued that the uses for the protein encoded by SEQ ID NO:1, for detecting, diagnosing, and treating cancer, are explicitly described in the specification (page 6 of Declaration and page 14 of Response, in particular).

The amendments to the claims and the arguments found in the Response and the Declaration filed on 11/22/05 have been carefully considered but are deemed not to be persuasive. As stated in the previous Office Action, the specification did not teach the protein sequence or the open reading frame of SEQ ID NO:1. Thus, the specification did not provide enough information to indicate for which protein the claimed antibody is specific. Therefore, the specification clearly does not describe a utility for an antibody with unknown specificity. Thus, one of ordinary skill in the art would doubt any truth to a stated utility. Further, as indicated above, there were routinely-used methods at the time of filing that would have enabled one of skill in the art to identify *potential* open reading frames from an mRNA sequence. However, as indicated in the figures provided with the Declaration, Applicants would identify multiple open reading frames using the tools described above with SEQ ID NO:1. One of skill in the art would have no reason to assume that the open reading frame would "encode many amino acids" and that the largest open reading frame identified by a computer program would be *the* protein encoded by SEQ ID NO:1. From the information provided in the specification, there is no reason to believe that the protein of SEQ ID NO:1 would

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not be encoded by other smaller open reading frames diagramed in the Declaration's figures. Therefore, since the specification does not identify "a protein encoded by polynucleotide SEQ ID NO:1", it cannot be determined to what the claimed antibody or antibody fragment will bind. Further, although Tringler and Salceda demonstrate utility of an antibody against "a" protein of SEQ ID NO:1, the specification did not teach "the" protein of SEQ ID NO:1. Therefore, utility of an antibody specific for a protein that the specification did not adequately describe is irrelevant. Essentially, the specification does not describe what the protein *is*. Thus, there is no utility for the claimed antibodies, antibody fragments, or methods of using said antibodies or said antibody fragments.

Claims 14, 21-28, 35-37 remain rejected and new claims 38-49 are rejected under 35 U.S.C. 112, first paragraph, because the claimed invention is not supported by either a substantial utility or a well established utility for the reasons of the previous Office Actions and for the reasons set-forth above.

Claims 14, 21-28, 35-37 remain rejected and new claims 38-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of the previous Office Actions and for the reasons set-forth above.

The Response filed on 11/22/05 has been carefully considered but is deemed not to be persuasive. It is noted that claims 14 and 28 have been amended to remove references to polynucleotide sequences other than SEQ ID NO:1. Further, the Response states that antibodies and their uses were described in detail and were claimed in the original specification (page 15 of Response). Further, Applicant states native protein and method for detection thereof are described in the original application (pages 15-16 of Response). Further, Applicant cites passages from the MPEP and case law, which are asserted to suggest that Applicant was in possession of the claimed invention at the time of filing. Applicant states "the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined in the claims. MPEP 2163 at page 2100-166; *In re Wertheim*, 541 F.2d 257 at 263, 191 USPQ 90 at 97 (CCPA 1976). Moreover, if the skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description is met. Also see *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Possession may be shown in a variety (of) ways including describing distinguishing identifying characteristics to show that applicants (were) in possession of the claimed invention. See MPEP 2163. Precisely how close [to the claimed invention] the description must come to comply with 112 must be left to case-by-case-development. *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96 (inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge

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imparted to those skilled in the art by the disclosure). Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. See MEPE 2163 at page 2100-73 and *Reagents of the University of California B. Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (Fed. Cir. 1997). Patents and printed publications in the art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention. See, e.g. *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534-1535, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992)." (Pages 16-17 of Response).

Further, the Response argues that Dr. Susana Salceda's Declaration indicates Applicant had a written description of the claimed invention. Specifically, Applicant

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argues that Dr. Salceda's Declaration indicates that sufficient distinguishing characteristics were taught in the specification so that using standard tools available to those skilled in the art as of the filing date of the instant application that every nuance of the protein sequence and/or the open reading frame of SEQ ID NO:1 could be routinely determined (pages 18-20 of Response). As described above, Dr. Salceda declared that there was only one possible open reading frame for the full-length protein encoded by SEQ ID NO:1 (page 13 of Response and frame 2 of Figure 2 from Declaration).

The amendments to the claims and the arguments found in the Response and the Declaration filed on 11/22/05 have been carefully considered but are deemed not to be persuasive. As stated above and in the previous Office Action, the specification did not teach *the* protein sequence or the open reading frame of SEQ ID NO:1. Thus, the specification did not provide enough information to indicate for which protein the claimed antibody is specific. As indicated above, there were routinely-used methods at the time of filing that would have enabled one of skill in the art to identify *potential* open reading frames from an mRNA sequence. However, as indicated in the figures provided with the Declaration, Applicants would identify multiple open reading frames using the tools described above with SEQ ID NO:1. One of skill in the art would have no reason to assume that the open reading frame would "encode many amino acids" and that the largest open reading frame identified by a computer program would be *the* protein encoded by SEQ ID NO:1. From the information provided in the specification, there is no reason to believe that the protein of SEQ ID NO:1 would not be encoded by other

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smaller open reading frames diagramed in the Declaration's figures. Therefore, since the specification does not identify "a protein encoded by polynucleotide SEQ ID NO:1", it cannot be determined to *what* the claimed antibody or antibody fragment will bind.

Therefore, it is determined that Applicant was not in possession of the claimed antibody or in possession of the protein to which the claimed antibody binds. Even though generating antibodies is rather routine in the art, it is not possible to make an antibody specific for an unknown protein. Essentially, the specification does not describe what the protein *is*. Thus, there is no written description for the claimed antibodies, antibody fragments, or methods of using said antibodies or said antibody fragments.

Summary

No claim is allowed.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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